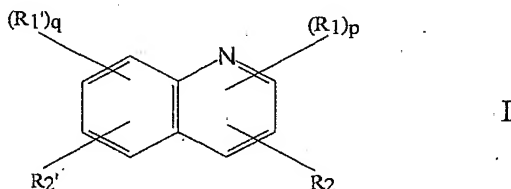


CLAIMS

1. A composition for ameliorating, treating, and preventing aphthous stomatitis and oral mucositis, comprising a quinoline derivative of formula I:



or a pharmaceutically acceptable salt thereof, wherein

R_1 and R_1' are independently selected from -H, -Cl, -F, C_1 - C_3 alkyl, C_1 - C_3 alkyloxy, and $-CF_3$;

R_2 and R_2' are independently selected from -H, $-NH(R_3)$, and $-C(OH)(R_3)$, wherein R_3 is selected from phenyl and C_3 - C_6 alkyl, substituted with 1 to 3 substituents selected from C_1 - C_2 alkyl, ethenyl, -OH, and $-NH_2$, and wherein said $-NH_2$ is either optionally substituted with one or two groups selected from ethyl and hydroxyethyl, or the nitrogen atom of said $-NH_2$ is connected with 1 or 2 carbon atoms of said C_3 - C_6 alkyl or C_1 - C_2 alkyl, possibly forming bicyclic structure;

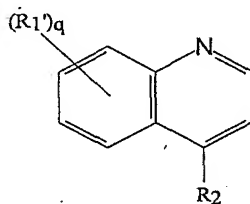
p is an integer from 1 to 3; and q is an integer from 1 to 4.

2. A composition according to claim 1, further comprising an antiseptic.
3. A composition according to claim 2, wherein said antiseptic is selected from the group consisting of chlorhexidine, thymol, and esters of p -hydroxybenzoic acid selected from methyl, ethyl, propyl, and butyl.
4. A composition according to claim 1 or 2, further comprising a constituent selected from solvents, buffers, carriers, binding agents, stabilizers, adjuvants, diluents, excipients, surfactants, flavors, and odorants.

5. A composition according to claim 1 or 2, further comprising another pharmaceutically active substance selected from analgesic, anti-inflammatory, antiviral, antibacterial, antifungal, antiseptic, and antineoplastic compounds.
6. A composition according to claim 2, wherein said antiseptic and quinoline derivative are applied subsequently, in any order.
7. A composition according to claim 2, wherein said antiseptic and quinoline derivative are applied simultaneously.
8. A composition according to claim 1 or 2, for topical use.
9. A composition according to claim 1, for oral delivery.
10. A composition according to claim 8, wherein said use comprises rinsing with liquid, or applying cream, ointment, gel, patch, or spray.
11. A composition according to any one of claims 1 to 10, wherein said stomatitis or mucositis comprises canker sores associated with aphtha minor, aphtha major, recurrent aphthous ulcers (RAU), recurrent aphthous stomatitis (RAS), herpetiform aphthae, vesicular-bullous erosive or ulcerative lesions, pemphigus family disorders, pemphigoid family disorders, linear IgA disorders or other immunoregulatory disorders, herpetiform dermatitis, discoid lupus erythematosus, radiotherapeutic mucositis, or chemotherapeutic mucositis.
12. A composition according to claim 11, wherein said mucositis or stomatitis is accompanied by a secondary infection.
13. A composition according to any one of claims 1 to 12, wherein in said quinoline derivative of formula I, as defined in claim 1,

R_1 and R_1' are independently selected from -Cl, -OCH₃, and -CF₃; one of R_2 and R_2' is -H, and one of R_2 and R_2' is selected from -NH(R_3), and -C(OH)(R_3), wherein R_3 is selected from phenyl and C₃-C₅ alkyl, substituted with 1 to 2 substituents selected from C₁-C₂ alkyl, ethenyl, and -NH₂, and wherein either said -NH₂ is optionally substituted with one or two groups selected from ethyl and hydroxyethyl, or the nitrogen atom of said -NH₂ is connected with 1 or 2 carbon atoms of said C₃-C₅ alkyl or C₁-C₂ alkyl, possibly forming bicyclic structure; and the sum of p and q is an integer from 1 to 3.

14. A composition according to any one of claims 1 to 13, wherein said quinoline derivative has formula II:



II

wherein

R_1' is selected from -Cl, C₁-C₃ alkyloxy, and -CF₃;

R_2 is selected from -NH(R_3), and -C(OH)(R_3), wherein R_3 is C₃-C₆ alkyl substituted with 1 to 3 substituents selected from C₁-C₂ alkyl, ethenyl, and -NH₂, and wherein said -NH₂ is either optionally substituted with one or two groups selected from ethyl and hydroxyethyl or the nitrogen atom of said -NH₂ is connected with 1 or 2 carbon atoms of said C₃-C₆ alkyl or C₁-C₂ alkyl, possibly forming bicyclic structure, and

q is 1 or 2.

15. A composition according to any one of claims 1 to 14, comprising a stereoisomer, or a mixture of stereoisomers, of a quinoline derivative according to claim 1.

16. A composition according to claim 15, wherein the compound of formula I is selected from quinine, quinidine, hydroxychloroquine, and a salt thereof.
17. A composition according to any one of claims 1 to 16, wherein said mucositis comprises canker sores associated with aphtha minor, aphtha major, recurrent aphthous ulcers, or recurrent aphthous stomatitis.
18. A composition according to claim 17, wherein said mucositis is accompanied by a secondary infection.
19. A composition according to any one of claims 1 to 18, wherein said quinoline derivative or said pharmaceutically acceptable salt thereof has a concentration of from 0.04 mg/ml to 10 mg/ml.
20. A composition according to claim 19, wherein said quinoline derivative or said pharmaceutically acceptable salt thereof has a concentration of from 0.05 mg/ml to 0.120 mg/ml.
21. A method for ameliorating, treating, and preventing an oral mucosa disorder, comprising
 - i) providing a quinoline derivative of formula I as defined in claim 1 or a stereoisomer thereof or a pharmaceutically acceptable salt thereof;
 - ii) optionally providing an antiseptic;
 - iii) preparing a one-component formulation comprising said quinoline derivative; or alternatively two-component composition comprising either two formulations containing separately said antiseptic and said quinoline derivative (or its isomer or salt), or one formulation comprising a mixture of said antiseptic and quinoline derivative in solution or suspension; wherein said formulations may further comprise constituents adjusting the consistency, stability, and olfactory properties, and optionally an additional active substances

- selected from analgesic, anti-inflammatory, antiviral, antibacterial, antifungal, antiseptic, and antineoplastic; and
- iv) administering said formulation or formulations to a patient in need of the treatment, wherein the two components in said two-component composition may be administered simultaneously or subsequently.
22. The method of claim 21, wherein said administration of said formulation or formulations comprises rinsing, spraying, and applying ointment or adhesive patch.
23. The method of claim 21, wherein said administration comprises rinsing with said formulation or formulations, and swallowing the formulation which comprises said quinoline derivative but not said antiseptic.
24. The method of claim 21, wherein said mucosa disorder is associated with aphtha, and wherein said administration comprises rinsing mouth several times a day.
25. The method of claim 22, wherein said rinsing comprises two liquids, one comprising an antiseptic, and the other a compound of formula I.
26. The method of claim 21, wherein said antiseptic is chlorhexidine in an alcohol-free water solution.
27. The method of claim 21, wherein said compound of formula I is selected from quinine, quinidine, hydroxychloroquine, and a salt thereof.